IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327 MDL 2327**
THIS DOCUMENT RELATES TO: *Ethicon Wave 8 Cases*	**JOSEPH R. GOODWIN U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF DR. VLADIMIR IAKOVLEV

Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon"), submit this memorandum in support of their motion to exclude the testimony of Dr. Vladimir Iakovlev. In Wave 8, Dr. Iakovlev offers new opinions on multifilament polyester mesh in addition to his prior opinions on monofilament polypropylene mesh. Because none of these opinions withstand *Daubert* scrutiny they must be excluded. The Ethicon MDL Wave 8 cases to which this motion applies are identified in Exhibit A.

INTRODUCTION

Dr. Iakovlev is a Canadian pathologist Plaintiffs have retained as an expert witness in hundreds of cases in this litigation. Until now, Dr. Iakovlev's expert testimony and research have focused on monofilament polypropylene mesh. In Wave 8, Dr. Iakovlev has submitted two sets of general causation opinions: 1) a general report focused on monofilament polypropylene mesh (unchanged from Wave 1), and 2) a new general report regarding the polyester multifilament mesh, Mersilene.

For those general opinions regarding monofilament polypropylene mesh previously disclosed in this litigation, Ethicon adopts and incorporates its prior briefing to exclude Dr. Iakovlev's opinions.

Prior to Wave 8, Dr. Iakovlev had never seen a Mersilene mesh. *See* Ex. B, Iakovlev 9/11/18 *Berden* Dep. Tr. 9:21-24. In his new Mersilene mesh general report, Dr. Iakovlev offers general causation opinions regarding Mersilene mesh, which is composed of polyethylene terephthalate (a material in the polyester family) and contains no polypropylene. However, Dr. Iakovlev has no basis for providing such opinions, having seen just one such mesh (the mesh explanted from Ms. Berden, a Wave 8 plaintiff) in his career. As a result, Ethicon seeks an order barring Dr. Iakovlev's general opinions regarding Mersilene mesh.

In arriving at his opinions, Dr. Iakovlev relied upon a small, cherry-picked set of literature involving Mersilene mesh. He failed to consider pertinent studies, failed to rely on Mersilene mesh publications from the last 17 years, mistook a Marlex mesh study for Mersilene mesh, improperly edited the complication rate found in one study, and deferred to others on how to interpret that same study. In an apparent attempt to bolster his limited review and reliance on the literature, Dr. Iakovlev attempts to draw comparisons between Mersilene mesh and other mesh types, including recycled opinions that were excluded by the court in the ObTape litigation. His opinions must be stricken due to his unreliable, limited analysis and understanding of Mersilene mesh as well as the inconsistency in his opinions (he places importance on design differences in understanding complications yet has no experience to compare the differences).

In addition, Dr. Iakovlev offers opinions regarding attitudes of surgeons and trends of device usage and design development that are speculative, unreliable, and far outside his

qualifications. Moreover, his use of an unvalidated web search tool to develop his data and subsequent reliance on that data is unreliable. These opinions should be also excluded.

ARGUMENT

I. Adoption of Prior Daubert Motion Regarding Dr. Iakovlev's General Opinions

Ethicon hereby adopts and incorporates by reference its Motion to Exclude the Opinions and Testimony of Dr. Vladimir Iakovlev [Dkt. #3619], and Ethicon's Memorandum of Law in Support of Motion to Exclude the Opinions and Testimony of Dr. Vladimir Iakovlev. [Dkt. #3621], previously filed in Wave 4. Ethicon respectfully asks this Court to exclude Dr. Iakovlev's testimony for the reasons expressed in the Wave 4 briefing adopted and incorporated herein, attached hereto as Exhibit C.

II. Dr. Iakovlev's General Opinions Regarding Mersilene Mesh Should be Excluded[1]

Dr. Iakovlev's Mersilene mesh opinions fall into two categories: 1) general opinions on multifilament mesh compared to monofilament mesh, without regard to the chemical composition of the material or other design features, and 2) general opinions specific to Mersilene mesh related to erosion and infection. Neither category passes *Daubert* scrutiny and, thus, Dr. Iakovlev's opinions should be excluded.

Dr. Iakovlev has offered numerous opinions in this MDL regarding monofilament polypropylene meshes, including meshes manufactured by Ethicon composed of Prolene or Prolene Soft, and his mesh work and research have focused on monofilament polypropylene

[1] This portion of the memorandum applies only to the Cheryl Berden case (Cheryl Berden, et al. v. Ethicon, Inc., et al., Case No. 2:14-cv-21966), as it is the only Wave 8 case in which Dr. Iakovlev has provided his general opinions regarding Mersilene mesh.

mesh. Dr. Iakovlev now seeks to offer general opinions on Mersilene mesh, which is a multifilament mesh made of polyethylene terephthalate (a material in the polyester family).[2]

Wave 8 is the first time Dr. Iakovlev has ever examined a Mersilene mesh under the microscope, as his prior experience, research, and litigation cases have focused on meshes constructed from polypropylene. *See* Ex. B, Iakovlev 9/11/18 Dep. Tr. 8:20-9:14 (he has reviewed 10 or fewer multifilament, polyester meshes, all of which were for hernias, and unknown to him if any were Mersilene); *id.* at 9:21-24 (Berden is first Mersilene mesh implanted in pelvic floor he has reviewed); *id.* at 12:2-6 (polypropylene has been focus of his work on implantable meshes); *id.* at 10:17-18 (no focus on multifilament mesh in his research); *id.* at 10:21-11:2, 11:21-12:1 (none of his publications deal with Mersilene mesh).

Dr. Iakovlev seeks to testify on the complications of erosion and infection with Mersilene mesh, and his general report is limited to these issues. *Id.* at 12:23-13:13. He also intends to testify regarding Mersilene's risks of erosion and infection in comparison to other meshes. His report describes a selection of studies, only a few of which discuss Mersilene. His methodology in assessing the literature is unreliable and, in any event, does not provide a sufficient basis for his opinions.

a. Legal Standard

Ethicon incorporates by reference the standard of review for Daubert motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at **1-3, (S.D. W. Va. July 8, 2014).

b. Opinions Based on Review of Other Mesh Specimens Should be Excluded as Unreliable and Unhelpful

[2] In contrast, Ethicon's Prolene and Prolene Soft meshes are monofilament meshes composed of Ethicon's proprietary polypropylene.

Dr. Iakovlev's opinions regarding Mersilene mesh draw heavily from his work with monofilament polypropylene mesh. His report discusses meshes other than Mersilene mesh and the complications of those meshes as if they are relevant to Mersilene mesh, while also opining that mesh design differences are important to understanding complications. Dr. Iakovlev makes no effort to reconcile the inconsistencies between these positions nor to establish the relevance of these meshes to his opinions. As a result, his opinions are unreliable and his opinions regarding other mesh products are irrelevant to Mersilene mesh.

Perhaps recognizing his lack of personal experience and limited literature review regarding Mersilene mesh, Dr. Iakovlev attempts to bolster his opinions with comparisons to other meshes. This is unreliable and Dr. Iakovlev does not provide a sufficient basis to conclude Mersilene mesh behaves the same way as other meshes. Such a conclusion would require Dr. Iakovlev to have experience with Mersilene mesh itself (in order to say it behaves in a way that is similar to the comparator meshes) and to undertake a comprehensive review of published literature on the product. Dr. Iakovlev's analysis of only one Mersilene mesh in his career is an insufficient basis for his opinions, as is his review of not more than 10 multifilament polyester hernia meshes. Dr. Iakovlev has not personally reviewed enough Mersilene meshes to offer the wide-ranging general opinions he seeks to offer and, as detailed more fully below, Dr. Iakovlev's opinions regarding the literature are unreliable and without sufficient basis. Without this experience and understanding of the literature, Dr. Iakovlev's opinions comparing non-Mersilene meshes to Mersilene mesh are pure speculation.

Any opinions Dr. Iakovlev offers relying upon his review of meshes other than Mersilene mesh (e.g., hernia meshes or meshes with differing designs) to bridge the gap to Mersilene mesh should be excluded. Dr. Iakovlev's own opinions foreclose his ability to reliably compare the

products because of the importance he has placed on the implantation location and on specific elements of mesh design. Further, Dr. Iakovlev makes no effort to recognize these differences and account for them in his opinions. For Dr. Iakovlev, the location of implantation is a "critical anatomic location" for mesh implantation in the pelvic floor. *See* Ex D, General Report of Dr. Vladimir Iakovlev, at 14.[3] In addition, he feels mesh design and characteristics of the material play important roles in the complications he seeks to discuss: erosion and infection. *See* Exhibit E, Supplemental Report of Dr. Vladimir Iakovlev for Issues Related to Mersilene Mesh, at 2 ("mesh specific factors play a role" in erosion), 3 ("characteristics of a material and the overall design of a device are the most important modifiable factors effecting [sic] the risk of infection." (emphasis added)); *see also* Ex. B, Depo. Tr. 17:12-13 (type of material matters), 16:14-17:4 ("So even if it's the same material, but different structure of a mesh, again, microporous will introduce extra risks for erosion than macroporous."). As a result, studies examining other meshes, implanted in other locations, for other indications, cannot support Dr. Iakovlev's opinions where he made no effort to account for his inconsistent positions or to address how the differences affect the complications he seeks to discuss.

Dr. Iakolev's effort to offer an opinion in an area in which he has no experience is similar to his opinions that were excluded in the ObTape litigation. In that litigation, as here, he tried to shoe-horn in his other polypropylene mesh opinions while also opining that devices have differences. *See Young v. Mentor Worldwide LLC*, 312 F. Supp. 3d 765 (E.D. Ark. 2018)

[3] Dr. Iakovlev's general report for polypropylene meshes lists several factors he felt relevant to his opinion that transvaginal implantation in the pelvic floor was a "critical anatomic location", including: 1) inability of mesh to expand and contract with nearby organs that expand and contract to function, 2) implantation under sensitive mucosa, 3) devices designed to provide support and press against organs, 4) placement through a contaminated field, 5) effect on nearby innervation and vascular supply, and 6) mesh arms and slings cross muscles and innervation network.

(general opinions excluded where Dr. Iakovlev reviewed only 10 ObTape specimens, all from counsel, and sought to testify regarding other, non-ObTape polypropylene meshes). In *Young*, the Court noted Dr. Iakovlev had testified:

> '[i]f we want to understand what is occurring after implantation of any polypropylene mesh of variable design, we have to know all this background[,] and we have to all these studies[,] and all the knowledge which was accumulated over the years. Then we can interpret accurately case-specific material.'

Id. at 771. Similar to his Mersilene mesh opinions here, Dr. Iakovlev sought to testify that ObTape carried a higher risk of erosion than other meshes. *See id.* ("Dr. Iakovlev concludes that the cumulative effects of ObTape design features result in 'higher mucosal erosion rates' and 'persistent infection that cannot be cleared by the body and can spread through the deep tissues.'"). As here, Dr. Iakovlev testified that complications are "somewhat different" depending on the mesh design. As a result, the Court found Dr. Iakovlev's opinions regarding other meshes to be irrelevant and excluded his opinions as unreliable. *Id.* at 771-78; *see also Clinton v. Mentor Worldwide LLC*, 2016 WL 7491861, No. 4:16-CV-00319 (CEJ) (E.D. Mo. 2016) (finding Dr. Iakovlev's general causation opinions regarding ObTape unreliable where Dr. Iakovlev based them on review of only four explanted ObTape meshes).

Despite Dr. Iakovlev's insistence on the importance of the implantation location and mesh design, he relies on a motley and insufficient set of information, to draw conclusions about Mersilene mesh. For example, he relies on information from:

- Hernia meshes composed of polypropylene, Ex. E, Suppl. Report at 2-8;
- Multifilament polypropylene slings (i.e., ObTape), *id.* at 11;
- Silicon strips and silicon coated meshes, *id.* at 2;
- Microporous GoreTex constructed with ePTFE, *id.* at 2; and
- Mersilene mesh implanted in the face, *id.* at 2.

Dr. Iakovlev's failure to follow his own stated principles renders his opinions unreliable, and his review of only one Mersilene mesh, provided to him in litigation, is not a sufficient basis upon which to compare Mersilene mesh complications with those occurring with (otherwise irrelevant) polypropylene meshes he has reviewed.

c. Dr. Iakovlev's Opinions Regarding Complications with Mersilene Mesh are Unreliable and are Not Supported by a Sufficient Basis

Dr. Iakovlev should not be permitted to testify regarding the risk of erosion or infection with Mersilene mesh or to compare the rate of those risks with other meshes. His opinions on these risks with Mersilene mesh are unreliable and lack a sufficient basis. Already working on a very small base of personal knowledge of Mersilene mesh, Dr. Iakovlev testified that there is not a large volume of literature on Mersilene used for sacrocolpopexy, Ex. B, Dep. Tr. 32:16-33:3, and that "if there is no large volume of literature, whatever is available is available," *id.* at 44:17-18. He included all studies he felt were directly relevant in his report. *Id.* at 22:18-23:5.

Because Dr. Iakovlev was not able to offer an overall rate of infection or erosion with Mersilene mesh, *see* Ex. B, Dep. Tr. 24:13-14, 25:25-26:6, 57:2-15, he should not be permitted to compare these complications with their occurrence with any other type of mesh. Dr. Iakovlev testified that complication rates were not important because the "[f]act that it can do it … that the complication exists is sufficient." *Id.* at 24:18-19. Yet despite the fact that he lacks this foundation, he seeks to testify that Mersilene mesh has a higher risk of infection and erosion than other mesh types. *See* Ex. E, Suppl. Report at 4, 8; Ex. B, Dep. Tr. 26:12-14 ("It may be variable, it can be somewhat different designs or devices, but overall class 3 meshes have higher risks of infection than class 1."). Without a complete understanding of Mersilene mesh's infection and erosion risks, which Dr. Iakovlev has not sought to determine, he should not be

permitted to testify to rates of these complications, including whether these complications occur more or less frequently with Mersilene mesh compared to other meshes.[4]

After declaring overall design as the "most important" factor in infection and that erosion risk is dependent on design, Dr. Iakovlev's opinion attempts to extrapolate general mesh concepts to Mersilene mesh without sufficient support. *See, e.g.*, Ex. E, Suppl. Report at 3-4. Having never reviewed a Mersilene mesh prior to Wave 8, Dr. Iakovlev turns to the medical literature related to Mersilene mesh to bolster his opinions. In doing so he employed a flawed review, which is made clear by his: 1) incomplete analysis of the body of relevant literature, 2) unscientific editing of findings he disagreed with, and 3) apparent inability to interpret certain literature he did analyze.

Dr. Iakovlev's reliance and recitation of medical literature involving Mersilene mesh is a very limited selection and it includes no peer-reviewed study published in the last 12 years. At most, Dr. Iakovlev's opinions on infection and erosion with Mersilene mesh involve 6 studies looking at only 421 patients implanted with Mersilene mesh. The insufficiency of Dr. Iakovlev's efforts is demonstrated by a single comprehensive review by Nygaard. In Nygaard's 2004 comprehensive review on abdominal sacrocolpopexy (ASC), the authors reported on 811 patients, from 8 different studies found in the peer-reviewed literature that determined an erosion rate for Mersilene mesh implanted through ASC. *See* Ex. F, Nygaard IE et al. *Abdominal sacrocolpopexy: a comprehensive review*. Obstet. Gynecol. 2004; 104(4): 805-23. Dr. Iakovlev does not cite this paper, nor six of the eight studies Nygaard considered to determine the erosion

[4] Allowing Dr. Iakovlev to provide such a comparison would be similar to comparing the taste of a Granny Smith apple to a Red Delicious apple when the only apples the person making the comparison has ever tasted are Red Delicious. Yes, they are both apples, but one cannot compare them without having experience with both.

rate.[5] Instead, Dr. Iakovlev's bases for his opinions are limited in both time (stopping at 2001) and scale (only 421 subjects).[6] Thus, Dr. Iakovlev's opinions on infection and erosion with Mersilene mesh are unreliable for similar reasons this Court has excluded other experts. *See, e.g., Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 520 (S.D.W. Va. 2014) (GOODWIN, J.), as amended (Oct. 29, 2014) ("An expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead 'selectively [chooses] his support from the scientific landscape.'") (*citing In re Rezulin Products Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y.2005)).

The unreliable nature of Dr. Iakovlev's opinion is demonstrated not only by his limited review of the literature, but by his treatment of the literature he did consider. For example, Dr. Iakovlev opines that "erosions, infections and formation of chronic sinus were reported in the 1990s for Mersilene mesh[,]" and cites two studies: 1) one study showing only two patients developed infection or chronic sinus, and 2) another that did not even examine Mersilene mesh.

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[5] The rate of erosion with Mersilene mesh reported in the Nygaard review was 3.1%. As discussed below, Dr. Iakovlev cites one study that reports an erosion rate of 5.5% -- though he asserts the "true" rate should be double or triple that number. Notably, Nygaard also considered this study, along with seven others, in the comprehensive review.

Likewise, Dr. Iakovlev failed to discuss the Mersilene mesh erosion rate reported in a 2006 review article that he cited for a chart classifying Mersilene mesh as "class III". *See* Ex. E, Suppl. Report at 8, n. 43 (citing Winters JC et al. *The use of synthetic mesh in female pelvic reconstruction surgery*. BJU Int'l. 2006; 98(1): 70-76). Perhaps this is because the review relies on Nygaard and lists the erosion rate with Mersilene mesh at 3.1%. *See* Ex. H, Winters JC et al. *The use of synthetic mesh in female pelvic reconstruction surgery*. BJU Int'l. 2006; 98(1): 70-76, at 73 (citing Nygaard IE et al. *Abdominal sacrocolpopexy: a comprehensive review*. Obstet. Gynecol. 2004; 104(4): 805-23).

[6] Where Nygaard reviewed studies reporting data on 811 patients implanted with Mersilene mesh in an abdominal sacrocolpopexy, Dr. Iakovlev's cumulative citation to studies involving only 421 patients includes Mersilene mesh implanted in the chin (66 patients), for hernia repair (51 patients), as stress urinary incontinence slings (12 patients), and for pelvic organ prolapse (292 patients).

See Ex. E, Suppl. Report at 8, n. 45 & 46. The latter study evaluated Marlex, a Type I monofilament polypropylene mesh, not Mersilene mesh. *See* Ex. B, Dep. Tr. 45:22-46:6 (testifying to his incorrect understanding that this study involved Mersilene); *see also* Exhibit G, Julian TM. *The efficacy of Marlex mesh in the repair of severe, recurrent vaginal prolapse of the anterior midvaginal wall*. Am. J. Obstet. Gynecol. 1996; 175(6): 1472-5. Dr. Iakovlev cited this Marlex study as Mersilene mesh because he mistakenly believed the publication was an example that the Mersilene mesh design can result in the relevant complications, Ex. B, Dep. Tr. 43:23-44:9, and that "it's a conclusion of the researchers who researched that specific type of mesh and for pelvic surgeries[,]" *id*. at 43:5-22 (included statement from study that "procedure is not recommended" for this reason). Instead, this study showed Type I Marlex mesh also carries a risk of infection, as well as demonstrating a mistaken impression underlying Dr. Iakovlev's unreliable opinions.

In evaluating the limited Mersilene mesh studies he did consider, Dr. Iakovlev also engaged in unreliable statistical manipulation, using no acceptable methodology or principle he could identify in any body of science, to conclude that the Mersilene mesh erosion rate reported in a study by Visco underestimates the "true" rate by at least half. *See* Ex. E, Suppl. Report at 8-9; *see also* Ex. B, Dep. Tr53:23-54:7 (testifying the study did not follow patients long enough to catch complications and that he expects they did not detect half of the complications). Dr. Iakovlev's opinion is unabashed speculation:

> Q. Is there any accepted method of estimating the complications that were not reported in the study, as you've done?
>
> A. I'm not estimating, I'm just estimating how much -- I'm just analyzing the median follow ups. There's no estimation. I don't know by how much they are underestimating. It can be double or triple, just based on the numbers. Again, there is no exact estimation, but there's obvious underreporting. And the degree of underreporting can be times, times two or times three.

Ex. B, Dep. Tr. 55:10-21. Eventually, Dr. Iakovlev admitted he cannot estimate the true complication rate in the study. *Id*. at 56:3-12. Cherry-picking studies is one thing (which Dr. Iakovlev does in his report), but Dr. Iakovlev also picks the cherries off the tree and seeks to tell the Court they are apples. Dr. Iakovlev provides no basis or methodology to permit him to double or triple the complication rate found in the peer-reviewed study. This is unreliable and should be excluded. *See Sanchez v. Boston Scientific Corp.*, 2014 WL 4851989, at *14 (S.D. W. Va. Sept. 29, 2014) (where an expert's complication rate opinions were excluded because the expert "'assume[ed] the worst-case scenario' and err[ed] on the side of opining as to a higher complication rate to better protect a patient."); *In re Digitek Prods. Liab. Litig.*, 821 F. Supp. 2d 822, 839 (S.D. W. Va. 2011) (an expert's opinions are inadmissible as "inconsistent with good science" if he makes "overreaching or speculative conclusions . . . based upon overreaching or speculative methodologies").

Dr. Iakovlev's flawed attempt to describe the incidence of erosion in his report led him to testify that he could not find sufficient studies upon which to base an erosion rate for Mersilene mesh. *See* Ex. B, Dep. Tr. 57:2-15. Given Dr. Iakovlev provides only one study for the rate of erosion in his report – and Dr. Iakovlev disagrees with the rate reported in that peer-reviewed publication -- Dr. Iakovlev should not be permitted to testify regarding the rate of erosion with Mersilene mesh, including whether it is higher than with other meshes. Without a reliable basis to determine the erosion rate with Mersilene mesh, Dr. Iakovlev cannot draw reliable conclusions about how Mersilene mesh compares to other meshes.

Finally, when questioned about the sole publication he relies upon for an erosion rate, Dr. Iakovlev admitted he was not versed well enough on the surgeries compared in the study to properly interpret it. He testified he would need to ask a urogynecologist to differentiate the

surgical procedures that formed the groups in the study. *See* Ex. B, Dep. Tr. 47:2-49:5. An "expert" should at a minimum be able to interpret the scientific literature he purports to rely upon and, in this case, criticize. Because he cannot, his opinions should be excluded.

d. Opinions Using ObTape as a Proxy for Mersilene Mesh Should be Excluded

Dr. Iakovlev's opinions regarding Mentor's ObTape device should be excluded as they are inconsistent with Dr. Iakovlev's other opinions, lack sufficient basis, and are simply an attempt to salvage his unreliable opinions on the risks of erosion and infection with Mersilene mesh. Unlike the Mersilene mesh specific opinions in his report, Dr. Iakovlev cites numerous product specific peer-reviewed publications to support the opinion that multifilament polypropylene mesh, implanted as a mid-urethral sling for the treatment of stress urinary incontinence, i.e., ObTape, showed rates of infection and erosion higher than monofilament designs.[7] *See* Ex. E, Suppl. Report at 11. As discussed previously, Dr. Iakovlev's same ObTape opinions were excluded by other courts in the ObTape litigation. Here, Dr. Iakovlev seeks to inject them into a Mersilene mesh case.

Failing to reliably demonstrate that Mersilene mesh has higher rates of infection and erosion than other meshes, Dr. Iakovlev uses the ObTape device as a proxy. Other than a shared characteristic of both being multifilament, Dr. Iakovlev does nothing to explain how the devices are otherwise similar or how their different material composition, pore size, weight, and many other differing characteristics, have no impact on erosion and infection rates. *See* Ex. E, Suppl. Report at 11. Dr. Iakovlev's own opinion that mesh design differences affect the risk for both complications make his deficiency significant. Moreover, Dr. Iakovlev admitted he is not aware if the erosion rate is higher or lower with ObTape compared to Mersilene mesh, *see* Ex. B, Dep.

[7] Dr. Iakovlev cites 19 studies about ObTape, which is not the product involved here.

Tr. 99:8-15, or how they compared vis-à-vis infection, *id*. at 99:16-21 ("One of them may be better; one of them may be worse"). As a result, Dr. Iakovlev's opinion is unreliable, speculative and, in the absence of relevant bases, he should not be permitted to offer testimony regarding complications associated with the ObTape device in any fashion and particularly as a proxy for Mersilene mesh.

e. Opinions Speculating on the Annual Number of PubMed Articles are Unreliable and Dr. Iakovlev is Not Qualified to Provide Them

Dr. Iakovlev attempts to use "data" gathered from the personal website of someone named Alexandru-Dan Corlan, whom Dr. Iakovlev does not know, *see* Ex. B, Dep. Tr. 39:6-12, to opine on the attitudes of surgeons, as well as development and usage of medical devices. *See* Ex. E, Suppl. Report at 12. The website used is a search engine of sorts that purports to provide the number of PubMed articles per year in which a search term is found. Dr. Iakovlev used the webpage to search "Mersilene" and, from that, extrapolated that infection and erosion with Mersilene mesh (and apparently ObTape) "affected use and introduction of new multifilament mesh designs." Ex. E, Suppl. Report at 12; *see also* Ex. B, Dep. Tr. 37:2-7 (using chart to demonstrate the "design did not take off").

Dr. Iakovlev is not qualified to provide an opinion on the attitudes of surgeons, their usage over time of medical devices, or whether certain information affected design and development of new devices. Nothing in his education, training, or research provides even a scintilla of qualification. Even if Dr. Iakovlev were qualified to discuss trends in medical device usage and design, his use of this website to generate data to extrapolate such findings is unreliable. Dr. Iakovlev did nothing to verify the methodology of this website, Ex. B, Dep. Tr. 39:16-18, and it is clear that Dr. Iakovlev's reliance on the results of his search for "Mersilene" ignored the warning found on the website itself:

> WARNING: Counting papers with a given feature is a very gross bibliometric method. Sometimes, the results are relevant, sometimes they require extensive checking, but they must always be interpreted very carefully.

http://dan.corlan.net/medline-trend.html (last visited Oct. 9, 2018). Dr. Iakovlev did no such checking found in the warning.

Finally, even if this personal website returned the actual number of "Mersilene" articles on PubMed by year, which Dr. Iakovlev could have verified by performing searches on PubMed, and even if Dr. Iakovlev were qualified to interpret this change, Dr. Iakovlev provides no basis for the conclusion that a reduction in this number over time demonstrates that knowledge of Mersilene's complications "affected use and introduction of new multifilament designs." *See* Ex. B, Dep. Tr. 38:11-20 (when asked for basis, he provided none but noted "it's just one of the indicators. It's not direct connection, it's one of the indicators.").

Because Dr. Iakovlev is not qualified to render these opinions, employed an unreliable methodology, and lacks a sufficient basis for his opinions, these opinions should be excluded.

CONCLUSION

For the foregoing reasons, Ethicon requests that the Court exclude the opinion testimony of Dr. Iakovlev, and issue an order for a hearing pursuant to Federal Rule of Evidence 104, and such other and further relief as the Court deems proper under the circumstances.

Dated: October 18, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on October 18, 2018, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

Respectfully submitted,

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